

REMARKS

Status of the Claims

Claims 17 -31 were previously pending and at issue. Claims 17, 18 and 28 have been amended. Claim 33 has been added. Accordingly, claims 17 - 31 and 33 are pending and at issue.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 17-31 stand rejected as failing to comply with the written description requirement. The Examiner states that the specification does not supply support for the full scope of the following limitation:

wherein the concentration of the dye is adjusted such that the fluorescent signal of the dye in the medium of the secondary standard after gelling the mixture is at least approximately equal to the fluorescent signal of a known concentration of the dye in a second medium

The Examiner states that the above language differs substantially from requiring "close mimicking of a primary standard".

While applicants respectfully disagree with the Examiner, to advance prosecution claims 17, 18 and 31 have been amended to recite "closely mimics" instead of "at least approximately equal to". Support for this amendment can be found, for example, on page 5, lines 19-21 of the application as filed.

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 17-31 stand rejected as indefinite. The Examiner states that it is unclear what constitutes the term "adjusted". More particularly, the Examiner states that the term adjusted implies that some dye is present and then some more is added or some [dye] or some is taken out in response to some determination, but that it is unclear if one simple addition is acceptable or if the claim requires the dye to be added in more than one step.

It would be clear to a person of ordinary skill in the art that the term "adjusted" refers to a trial and error technique in which the concentration of the dye is altered based on the results of a previous trial. The previous trial could be in connection with the standard being instantly produced, or based on knowledge previously obtained using a standard having the same specifications as the standard being instantly produced. Accordingly, one simple addition step would fall within the scope of these claims if this addition step is based on the results of a trial and error technique performed on another standard having the same specifications.

The Examiner implies that any amount of dye would always give a fluorescent signal that is equivalent to the fluorescent signal corresponding to a known concentration of dye in a second medium. The Examiner also states that since the instant claims do not require analyzing anything and do not require anything to have been analyzed, it is unclear how one is required to know the concentration of any dye or to have considered all of the factors of any given analyte medium that affect the final fluorescent signal.

The claims inherently require the determination of the fluorescent signal of a known concentration of dye in the medium of the analyte measurement. This is because the concentration of the dye is adjusted to provide the same fluorescent signal in the more stable medium of the secondary standard. This would be understood based, for example, on the disclosure on page 14 of the specification, which states:

The dye's real concentration is adjusted to yield fluorescence intensities equaling that of a primary standard, 100 nM Cy3 in TRIS/HCl buffer (pH 8) . . . It is understood that other dyes, or plate formats, can be easily substituted, with concentrations adjusted to yield intensities equal to the desired primary standards.

(Specification, lines 9-13) In other words, it is clear to a person of ordinary skill in the art that in order to adjust the concentration of a dye such that the fluorescence of the dye in one medium equals that of a second medium, the fluorescence of the dye in both mediums would have to be ascertained.

It is important to note that the claims refer to two distinct mediums. The first medium (referred to in the claim as the medium of the secondary standard) is more stable and is described generally on page 8, lines 5-17 of the specification. The second medium is the medium that is used in the normal assaying process (referred to in the claims as the second medium of the analyte sample measurement).

In the Example described on page 14 of the specification, the medium of the secondary standard includes Polyphobe TR116, a alkali-swellaable urethane-modified rheology modifier. The concentration of the dye in this medium is adjusted so that its fluorescence is equal to a known concentration of dye in the medium for which subsequent assaying techniques are performed. The claims inherently require a) that the fluorescence of a known, i.e. pre-selected, concentration of dye in the medium of the subsequent assaying technique first be determined, and b) adjustment the concentration of the dye such that it provides an equivalent fluorescence in the medium of the secondary standard. The two standards are different, and thus have unique characteristics that would affect the fluorescence of the dye. It cannot be said that any amount of dye in the medium of the secondary standard would necessarily yield the same fluorescent signal as the fluorescent signal provided by the known amount of dye in medium that will ultimately be used to perform the assays after standardization.

To advance prosecution, claims 17, 18 and 28 have been amended to specify that the medium of the secondary standard is different and more stable than the medium of the analyte sample measurement. Claim 33 has also been added, which more positively recites inherent features of the previously pending claims.

Rejections Under 35 U.S.C. §§ 102 and 103

Claims 17-23, 27 and 30-31 stand rejected as anticipated by Cote (U.S. Pat. No. 6,485,703).

The Examiner relies on the compositions in Cote that include pH sensitive dyes and hydrogels that undergo a phase change.

In response to the limitation that "wherein the medium of the secondary standard is different that the second medium of the analyte sample measurement" the Examiner states:

Inherent in [Cote's abstract] that the hydrogel particles are useful to detect one or more selected analytes and the fact that the thing being detected is the dye in the hydrogel, i.e. the medium of the secondary standard has to give a signal corresponding to something in the analyte medium whether the analyte medium is the same as the hydrogel or different.

Thus, the Examiner states that the thing being detected has to give a signal corresponding to something in the analyte medium regardless of whether it is the same or different, but the Examiner does not show where Cote discloses determining a signal in a medium that *is* different than the medium used to assay the analyte of interest.

As noted above, claims 17 and 18 to recite "wherein the medium of the secondary standard is different and more stable than the second medium of the analyte sample measurement. Support for this amendment can be found, for example, on page 7, lines 10-12 of the application as filed. The Examiner is respectfully requested to point out where Cote discloses determining a signal in a medium that is different and more stable than the second medium of the analyte system measurement.

Applicants also refer to newly added claim 33, in which inherent features are more positively recited, and the limitation "triggering a viscosifying gelation reaction to gel the mixture" is added. This limitation is supported, for example, by page 8, lines 13-14 and page 14, line 15 of the application as filed.

Claims 17-31 stand rejected as obvious over Cote in view of Little (U.S. Pat. No. 6,077,669). The Examiner relies on column 8 of Little which purportedly discloses a standardization technique.

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Like Cote, little does not disclose or suggest, inter alia, determining a signal in a medium that is different and more stable than the second medium of the analyte system measurement. The Examiner is respectfully requested to point out where this limitation is disclosed or suggested in Little.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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